



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Jerome F. McAleer et al.

Serial No.

09/869,887

Art Unit: 1753

Filed

February 20, 2002

Examiner: Noguerola, A.S.

For

Disposable Test Strips With Integrated Reagent/Blood Separation Layer

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

10/06/2004 LWONDIM1 00000020 100750

09869887

01 FC:1806

180.00 DA

(Date of Signature)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required. In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with the first or second After Final Submission, therefore: Statement in Accordance with §1.97(e) (attached); or Please charge Deposit Account No. 10-0750/ the fee of \$180.00 as set forth in \$1.17(p). 冈 In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of: Statement in Accordance with §1.97(e) (attached); or X Please charge Deposit Account No. 10-0750/DDI-005/BES the fee of \$180.00 as set forth in \$1.17(p). In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in \$1.17(p).

\bowtie	Copies of each of the references listed on the attached Form PTO-1449 are
enclosed here	ewith.
	Copies of references listed on the attached Form PTO-1449 are enclosed
herewith EXC	CEPT THAT:
	In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
	If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
publication lisapplication was national stage	Copies of only foreign patent documents and non-patent literature are enclosed with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application sted on the attached Form PTO-1449 are not enclosed because this U.S. patent as filed after June 30, 2003 or this international application has entered the under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement & 1.98 (a)(2)(i).
	There are no listed references which are not in the English language.
as follows:	The relevance of those listed references which are not in the English language is
which are list	Attached are copies of search report(s) from corresponding patent application(s), ed on the attached Submission Under MPEP 609 D.
may be deeme	Attached are the following non-published pending patent applications which ed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/DDI-005/BES. This form is submitted in triplicate.

Respectfully submitted,

Bernard E. Shay

Reg. No. 32,061

Attorney for Applicants

Johnson & Johnson International Patent Law Division Attention Philip Johnson P.O. Box 1222 New Brunswick, NJ 08903 (408) 956-4066 DATED: 2/3 %



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 1 of 3

a consection of intermediator among it displays		
Application Number	09/869,887	
Filing Date	February 20, 2002.	
First Named Inventor	McAleer	
Group Art Unit	1753	
Examiner Name	Noguerola, A.S.	
Attorney Docket Number	DDI-005	

		Sheet 1 of	3			
		T 2 2		U.S. PATENT DOCUMENTS		
Examiner Initials	Cite		d Code ² known)	Name of Patentee or Applicar of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	
		4,195,129		Fukui et al.	03/25/80	
		4,418,148		Oberhardt	11/29/83	
		4,655,880		Liu	04/07/87	
		4,876,205		Green et al.	10/24/89	
		4,966,671		Nylander et al.	10/30/90	
		5,120,420		Nankai et al.	06/09/92	
		5,124,253		Foulds et al.	06/23/92	
		5,126,034		Carter et al.	06/30/92	
		5,141,868		Shanks et al.	08/25/92	
		5,262,035		Gregg et al.	11/16/93	
		5,264,106		McAleer et al.	11/23/93	
		5,286,362		Hoenes et al.	02/15/94	
		5,288,636		Polimann et al.	02/22/94	
		5,378,628		Gratzel et al.	01/03/95	
		5,437,999		Diebold et al.	08/01/95	
		5,565,085		Ikeda et al.	10/15/96	
		5,582,697		Ikeda et al.	12/10/96	
		5,582,698		Flaherty et al.	12/10/96	
		5,601,694		Maley et al.	02/11/97	
		5,708,247		McAleer et al.	01/13/98	
		5,185,256		Nankai et al.	02/09/93	

		
Examiner	 Date	i ·
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)
Sheet 2 of 3

a concentration and an array and a state of the contract forms of				
Application Number	09/869,887			
Filing Date	February 20, 2002			
First Named Inventor	McAleer			
Group Art Unit	1753			
Examiner Name	Noguerola, A.S.			
Attorney Docket Number	DDI-005			

	U.S. PATENT DOCUMENTS						
Examiner Initials	Cite No.1	U.S. Patent Do	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document mm-dd-yyyy	Pages, Columns, Lines, where relevant passages or relevant figures appear	
•							

FOREIGN PATENT DOCUMENTS Foreign Patent Document Date of Publication Pages, Columns, Lines, of Cited Document where relevant Name of Patentee or passages or relevant Examiner Cite mm-dd-yyyy Applicant of Cited Document figures appear Initials Office³ Number⁴ KindCode⁵ No.1 0127958 В2 MediSense, Inc. 04/10/96 0170375 Unilever PLC 05/16/90 ΕP В1 0207370 В1 Miles Inc. 04/14/93 wo 89/08713 Α1 Life-Chek Laboratories 09/21/89 94/27140 MediSense, Inc. 11/24/94 wo Α1 Α1 01/23/97 97/02487 Boehringer Mannheim Coproration

_				
	Examiner	,	Date	
	Signature		Considered	

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. 2 See attached Kinds of U.S. Patent Documents. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary) Sheet 3 of 3

a conscitor of information trices it displays a	Valid Civid Control Hamber.
Application Number	09/869,887
Filing Date	February 20, 2002
First Named Inventor	McAleer
Group Art Unit	1753
Examiner Name	Noguerola, A.S.
Attorney Docket Number	DDI-005

	OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS						
		Include name of the author (in CAPITOL LETTERS), title of the article (when appropriate), title of the item					
Examiner's	Cite	(book, magazine, journal, senal, symposium, catalog, etc.), date, page(s), volume-issue number(s),	T ²				
Initials*	No.1	publisher, city and/or country where published					
		Abstract of JP55010583 "Enzyme Electrode and its Manufacture" Shiro Nankai et al., 19890-01-25.	T				
		Abstract of JP55010584 "Enzyme Electrode and its Manufacture" Shiro Nankai et al., 1980-01-25.					
		Abstract of JP55010581 "Enzyme Electrode" Shiro Nankai et al., 1980-01-25.					
		Abstract of JP55124060 "Enzyme Electrode" Shiro Nankai et al., 1980-09-24.					
			ļ				
	Ļ						
	<u> </u>						
			ļ				
			-				
	<u> </u>						
			 				
	 		-				
	 		 				
	L		 				
	 		 				
			├				
	I	·	1				

Examiner	Date	
Signature	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA